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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/640,737	08/17/2000	Eva-Maria Mandelkow	28384/36668	5085

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Marshall O'Toole Gerstein Murray & Borun
6300 Sears Tower
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Chicago, IL 60606-6402

EXAMINER

CHERNYSHEV, OLGA N

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 07/30/2003

85

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/640,737

Applicant(s)

MANDELKOW ET AL.

Examiner

Olga N. Chernyshev

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 37-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 37-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 August 2000 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☒ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 08/244,603.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group XXII in Paper No. 17 is acknowledged. The traversal is on the ground(s) that the peptides of the Markush group share a common utility as being useful in producing antibodies specific for the tau protein, and, also, the common utility is based upon a shared structural feature because each peptide of the Markush group is derived from the same tau protein. These arguments have been found to be persuasive in part. The Examiner acknowledges that because fragments of tau peptide of SEQ ID NO: 1 are asserted to be useful in producing antibodies and, therefore, share a common utility, the objections to the claims as being improper Markush claims is withdrawn. However, because each of the recited sequences represents a non-overlapping fragment of a larger sequence and each fragment could be embedded within other patentably distinct proteins, a separate search is required for each possible fragment, the restriction is still deemed proper. Moreover, it is burdensome to search more than a single sequence in an application.

The requirement is still deemed proper and is therefore made FINAL.

Claims 37-50, in so far as they are directed to a composition comprising a peptide of SEQ ID NO: 1, residues 259-267, are under examination in the instant office action.

Drawings

2. The figures of the instant application are presented on separate pages or in separate panels. 37 C.F.R. § 1.84(u) (1) states that when partial views of a drawing which are intended to form one complete view, whether contained on one or several sheets, must be identified by the

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same number followed by a capital letter. For example, Figures 1a and 1b should be presented as 1A and 1B. Furthermore, for example, the two pages of Figure 9 in the instant specification should be renumbered “Figure 9A” – “Figure 9C” rather than “Figure 9”. Applicant is reminded that once the drawings are changed to meet the separate numbering requirement of 37 C.F.R. § 1.84(u) (1), the specification should be amended to change the Brief Description of the Drawings and the rest of the specification to refer to each Figure accordingly. If, for example, Figure 9 is divided into Figures 9A-9C, then the Brief Description and all the references to this figure in the specification must refer to this Figure in the same manner.

Furthermore, it appears that in some case discrepancies in description of the figures exist. For example, Figure 1b is described as containing parts (a) and (b) (see page 23 of the instant specification). However, parts (a) and (b) are not properly identified within Figure 1b.

Applicant is advised to review all the figures of the instant specification for proper presentation and identification.

Specification

3. Table 1 presented on page 87 of the instant specification does not comply with 37 C.F.R. 1.58 (c) with respect to font size:

Chemical and mathematical formulae and tables must be presented in compliance with § 1.52(a) and (b), except that chemical and mathematical formulae or tables may be placed in a landscape orientation if they cannot be presented satisfactorily in a portrait orientation. Typewritten characters used in such formulae and tables must be chosen from a block (nonscript) type font or lettering style having capital letters which are at least 0.21 cm. (0.08 inch) high (e.g., elite type). A space at least 0.64 cm. (1/4 inch) high should be provided between complex

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formulae and tables and the text. Tables should have the lines and columns of data closely spaced to conserve space, consistent with a high degree of legibility.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 37-50 are rejected under 35 U.S.C. 102(b) as being anticipated by Kosik et al.

(Proc. Natl. Acad. Sci., USA, 1986, Vol. 83, pp.4044-8).

Claims 37-43 are directed to an immunogenic composition comprising a peptide consisting essentially of a fragment 259-267 of SEQ ID NO: 1. Claims 44-50 are directed to a method of producing an antibody to a tau peptide by administration to an animal an immunogenic composition comprising a peptide consisting essentially of a fragment 259-267 of SEQ ID NO: 1. SEQ ID NO: 1 of the instant application represents tau protein (see Figure 1a). Due to the use of the transitional phrase “consisting essentially of” the instant claims encompass an immunogenic composition comprising entire tau protein of SEQ ID NO: 1. See MPEP 2111.03, Transitional Phrases:

The transitional phrases “comprising”, “consisting essentially of” and “consisting of” define the scope of a claim with respect to what unrecited additional components or steps, if any, are excluded from the scope of the claim. For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the

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basic and novel characteristics actually are, “consisting essentially of” will be construed as equivalent to “comprising.” See, e.g., PPG, 156 F.3d at 1355, 48 USPQ2d at 1355 (“PPG could have defined the scope of the phrase consisting essentially of” for purposes of its patent by making clear in its specification what it regarded as constituting a material change in the basic and novel characteristics of the invention.”). See also *In re Janakirama-Rao*, 317 F.2d 951, 954, 137 USPQ 893, 895-96 (CCPA 1963).

Kosik et al. disclose immunogenic protein composition comprising tau protein, which was prepared from purified PHF (paired helical filaments) fractions of postmortem tissue of patients suffering from Alzheimer’s disease, and a method of producing an antibody to tau peptide by immunization with tau fraction (see the abstract on page 4044 and the entire paper). Because of the similarity of the preparation of tau from Alzheimer’s brain described in the instant specification (page 45-46) and disclosed by Kosik et al., the pattern of phosphorylation of the specific residues of the fragment 259-267 of SEQ ID NO: 1 is expected to be the same, absent evidence to the contrary. Thus, publication of Kosik et al. anticipates the invention of the instant claims 37-50.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002

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do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 37-50 rejected under 35 U.S.C. 102(e) as being anticipated by Vooheis, US Patent No.5,492,812, 1996, filed on 08/01/1991.

Vooheis discloses a sequence (SEQ ID NO: 2), which has 100% identity to a fragment 259-267 of SEQ ID NO: 1 of the instant application (see a copy of the sequence alignment attached to the instant office action). Vooheis also discloses the purification of tau-proteins from human brains of patients who died with Alzheimer's disease (columns 7-8) and methods of generation of antibodies that define tau-peptides (columns 12 and 13). Thus, for reasons of record as applied to claims 37-50 in section 4 of the instant office action, the disclosure of Vooheis meets the limitations of claims 37-50.

Double Patenting

6. In view of the elected invention of a composition comprising a peptide of SEQ ID NO: 1, residues 259-267, Applicant is advised that should claim 37 be found allowable, claims 38 and 39 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. Also, should claim 44 be found allowable, claims 45 and 46 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. Furthermore, should claims 40 and 47 be found allowable, claims 42 and 49, respectively, will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they

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both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Conclusion

7. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (703) 305-1003. The examiner can normally be reached on Monday to Friday 9 AM to 5 PM ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (703) 308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 782-9306 for regular communications and (703) 782-9307 for After Final communications.

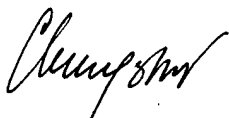
Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

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Official papers filed by fax should be directed to (703) 308-4556 or (703) 308-4242. If either of these numbers is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. Official papers should NOT be faxed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Olga N. Chernyshev, Ph.D.
July 23, 2003

A handwritten signature in black ink, appearing to read "Chernyshev", is written over the typed name and date.